

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) An implantable cardiac lead system, comprising:

 a lead body comprising a rigid elongated support structure;

 a cardiac electrode supported by the lead body, the electrode configured for subcutaneous, non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

an implantable can coupled to the lead body, the rigid elongated support structure of the lead configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient;

 one or more conductors coupled to the cardiac electrode and disposed within the lead body;

 a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body; and

 a driving arrangement coupled to the lead, the driving arrangement comprising a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer, the driving arrangement configured to provide sonophoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body to subcutaneous tissue by electrical activation of the conducting surface coating causing movement of the polyvinylidene fluoride layer.

2. (Currently amended) The lead system according to claim 1, wherein the lead body and the implantable can form a unitary structure having an arcuate shape driving arrangement comprises the electrode supported by the lead body.

3. (Currently amended) The lead system according to claim 1, wherein the rigid elongated support structure is configured to maintain the cardiac electrode and a second electrode on the can in opposition with respect to the ventricles of the heart ~~driving arrangement comprises a transducer adapted to provide sonephoresis.~~

4. (Currently amended) The lead system according to claim 1, wherein the polyvinylidene fluoride layer and the conducting surface coating are provided along the longitudinal portion of the exterior surface of the lead body ~~electrode is configured as an electrode array, and the driving arrangement comprises the electrode array.~~

5. (Currently amended) The lead system according to claim 1, further comprising an implantable pharmacological agent reservoir, wherein the lead body further comprises a lumen in fluid communication with the reservoir ~~configured to facilitate transport of pharmacological agent stored in the reservoir through the lead driving arrangement~~ comprises a conductor adapted to provide electrophoresis.

6. (Currently amended) The lead system according to claim 4-5, further comprising a micro-pump ~~configured to facilitate transport of pharmacological agent from the reservoir through the lumen to the exterior surface of the lead body~~ wherein the pharmacological agent provides therapeutic treatment localized to an area substantially surrounding at least a portion of a subcutaneous dissection path.

7. (Currently amended) The lead system according to claim 1, wherein the driving arrangement is configured to generate an acoustic field that impels the pharmacological agent into subcutaneous, non-intrathoracic tissue ~~is provided at least along a plurality of longitudinal portions of the exterior surface of the lead body.~~

8. (Currently amended) The lead system according to claim 1, wherein the pharmacological agent is disposed along the conducting surface coating impregnated into a membrane provided along the longitudinal portion of exterior surface of the lead body.

9. (Currently amended) The lead system according to claim 1, wherein at least part of the driving arrangement comprises an external driver detachably coupled to the lead system, the external driver configured to provide power and control for phoresis delivery of the pharmacological agent during surgical implantation of the lead body lead further comprises a collar provided along the longitudinal portion of the exterior surface of the lead body, the pharmacological agent provided at the collar.

10. (Currently amended) The lead system according to claim 1, wherein the driving arrangement is configured to generate an ultrasonic field that drives the pharmacological agent into subcutaneous, non-intrathoracic tissue lead further comprises a polymeric structure provided along the longitudinal portion of the exterior surface of the lead body, the pharmacological agent infused within the polymeric structure.

11. (Currently amended) The lead system according to claim 1, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy wherein the lead further comprises a porous region provided along the longitudinal portion of the exterior surface of the lead body, the pharmacological agent at least partially filling pores of the porous region.

12. (Currently amended) The lead system according to claim 1[1], further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative

to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy wherein the porous region comprises a doped polymer matrix.

13. (Currently amended) The lead system according to claim 1, wherein the pharmacological agent is disposed in a coating provided along the longitudinal portion of the exterior surface of the lead body.

14. (Currently amended) The lead system according to claim 1, wherein the rigid elongated support structure has a mechanical memory such that the lead body retains a configuration after being shaped by a clinician under manual force and generally retains the configuration after implantation pharmacological agent comprises an analgesic or an anesthetic.

15. (Currently amended) The lead system according to claim 1, wherein the driving arrangement is configured to deliver a DC voltage to the conducting surface coating to provide sonophoresis delivery of the pharmacological agent comprises an antibiotic or an antiseptic.

16. (Currently amended) The lead system according to claim 1, wherein the driving arrangement is configured to deliver an AC signal alternating at an ultrasonic frequency to the conducting surface coating to provide sonophoresis delivery of the pharmacological agent comprises a steroid or an anti-inflammatory agent.

17. (Currently amended) The lead system according to claim 1, wherein the driving arrangement is configured to deliver a DC bias voltage with an AC signal alternating at an ultrasonic frequency to the conducting surface coating to provide sonophoresis delivery of

~~the pharmacological agent comprises an agent that promotes hemostasis or provides vasorestriction.~~

18. (Currently amended) An implantable system, comprising:

a lead, comprising:

a lead body; and

a cardiac electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

a can coupled to the lead; and

a pharmacological agent provided on a portion of an exterior surface of the can; and[.]

a driving arrangement coupled to the can, the driving arrangement comprising a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer, the driving arrangement wherein the can is configured to provide sonophoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can to subcutaneous tissue by electrical activation of the conducting surface coating and movement of the polyvinylidene fluoride layer.

19. (Currently amended) The system according to claim 18, wherein the driving arrangement is configured to generate an acoustic field that impels the pharmacological agent into subcutaneous, non-intrathoracic tissue~~can is configured to provide electrophoresis.~~

20. (Currently amended) The system according to claim 18, wherein the driving arrangement is configured to generate an ultrasonic field that drives the pharmacological agent into subcutaneous, non-intrathoracic tissue~~can is configured to provide sonophoresis.~~

21. (Currently amended) The system according to claim 18, further comprising an implantable pharmacological agent reservoir and a micro-pump configured to facilitate transport of pharmacological agent from the reservoir to the exterior surface of the can-a driving arrangement provided on the lead and configured to provide phoresis delivery of a pharmacological agent from at least a portion of the lead to the subcutaneous tissue.

22. (Currently amended) The system according to claim 18, wherein the ~~lead and the can are configured to produce an electric potential between the lead and the can, the electric potential produced to provide the phoresis delivery of the pharmacological agent~~ is disposed along the conducting surface coating.

23. (Currently amended) The system according to claim 18, wherein the at least part of the driving arrangement comprises an external driver detachably coupled to the can, the external driver configured to provide power and control for phoresis delivery of the pharmacological agent during surgical implantation of the can is impregnated into a membrane provided on the portion of the exterior surface of the can.

24. (Canceled).

25. (Previously presented) The system according to claim 18, wherein the can comprises a porous region on the portion of the exterior surface, the pharmacological agent at least partially filling pores of the porous region.

26. (Original) The system according to claim 25, wherein the porous region comprises a doped polymer matrix.

27. (Currently amended) The system according to claim 18, further comprising a lead body coupled to the can, the lead body and the can forming a rigid unitary structure having an arcuate shape wherein the pharmacological agent is disposed in a coating on the portion of the exterior surface of the can.

28. (Original) The system according to claim 27, wherein the coating covers at least 25% of a surface area of the can.

29. (Currently amended) The system according to claim 18, further comprising a lead coupled to the can, the lead comprising an electrode and a rigid elongated support structure configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient wherein the pharmacological agent comprises an analgesic or an anesthetic.

30. (Currently amended) The system according to claim 18, wherein the polyvinylidene fluoride layer and the conducting surface coating are provided along the exterior surface of the can pharmacological agent comprises an antibiotic or an antiseptic.

31. (Currently amended) The system according to claim 18, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy wherein the pharmacological agent comprises a steroid or an anti-inflammatory agent.

32. (Currently amended) The system according to claim 18, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy wherein

~~the pharmaceutical agent comprises an agent that promotes hemostasis or provides vasoconstriction.~~

33. (Withdrawn) A method of lead implantation, comprising:

delivering a lead into subcutaneous non-intrathoracic tissue of a patient, the lead comprising a lead body, a cardiac electrode configured for one or both of cardiac monitoring and cardiac electrical stimulation, and a pharmaceutical agent on the lead; and

impelling, using phoresis, the pharmaceutical agent from at least a portion of the lead to the subcutaneous non-intrathoracic tissue.

34. (Withdrawn) The method according to claim 33, wherein impelling the pharmaceutical agent comprises generating an electric field for impelling the pharmaceutical agent using electrophoresis.

35. (Withdrawn) The method according to claim 33, wherein impelling the pharmaceutical agent comprises generating ultrasonic waves for impelling the pharmaceutical agent ultrasonically.

36. (Withdrawn) The method according to claim 33, wherein impelling the pharmaceutical agent using phoresis comprises impelling a plurality of pharmaceutical agents.

37. (Withdrawn) The method according to claim 33, wherein impelling the pharmaceutical agent comprises impelling a first pharmaceutical agent using electrophoresis and impelling a second pharmaceutical agent using sonophoresis.

38. (Withdrawn) The method according to claim 33, further comprising

delivering a can into subcutaneous non-intrathoracic tissue of the patient, the can comprising an electrode or an electrically conductive region, and a pharmacological agent; and

impelling, using phoresis, the pharmacological agent from at least a portion of the can to the subcutaneous non-intrathoracic tissue.

39. (Withdrawn) The method according to claim 38, wherein impelling the pharmacological agent from the can comprises generating an electric field for impelling the pharmacological agent from the can using electrophoresis.

40. (Withdrawn) The method according to claim 38, wherein impelling the pharmacological agent comprises generating ultrasonic waves for impelling the pharmacological agent ultrasonically from the can.

41. (Withdrawn) The method according to claim 38, wherein impelling the pharmacological agent from the can using phoresis comprises impelling a plurality of pharmacological agents from the can.

42. (Withdrawn) The method according to claim 38, wherein impelling the pharmacological agent from the can comprises impelling a first pharmacological agent using electrophoresis and impelling a second pharmacological agent using sonophoresis.

43. (Withdrawn) The method according to claim 33, further comprising:

providing a removable sheath having a lumen;

advancing the lead through the lumen to an implant location; and

removing the sheath from the lead with the lead remaining at the implant

location.

44. (Withdrawn) The method according to claim 33, wherein the pharmacological agent comprises an analgesic or an anesthetic.

45. (Withdrawn) The method according to claim 33, wherein the pharmacological agent comprises an antibiotic or an antiseptic.

46. (Withdrawn) The method according to claim 33, wherein the pharmacological agent comprises a steroid or an anti-inflammatory agent.

47. (Withdrawn) The method according to claim 33, wherein the pharmacological agent comprises an agent that promotes hemostasis or provides vasoconstriction.

48. (Currently amended) An implantable cardiac lead system, comprising:

 a lead body comprising a rigid elongated support structure;

 a cardiac electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement in a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

an implantable can coupled to the lead body, the rigid elongated support structure of the lead configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient;

 one or more conductors coupled to the electrode and disposed within the lead body;

 a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body; and

 means, coupled to the implantable lead, for impelling the pharmacological agent using phoresis from the longitudinal portion of the exterior surface of the lead body into subcutaneous non-intrathoracic tissue.

49. (Currently amended) The lead system according to claim 48, wherein the impelling means comprises means for impelling the pharmacological agent using electrophoresis.

50. (Currently amended) The lead system according to claim 48, wherein the impelling means comprises a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer that provide means for impelling the pharmacological agent using sonophoresis by electrical activation of the conducting surface coating causing movement of the polyvinylidene fluoride layer.

51. (Currently amended) The lead system according to claim 48, wherein the lead body and the implantable can form a unitary structure having an arcuate shape pharmacological agent comprises an analgesic or an anesthetic.

52. (Currently amended) The lead system according to claim 48, wherein the polyvinylidene fluoride layer and the conducting surface coating are provided along the longitudinal portion of the exterior surface of the lead body pharmacological agent comprises an antibiotic or an antiseptic.

53. (Currently amended) The lead according to claim 48, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy wherein the pharmacological agent comprises a steroid or an anti-inflammatory agent.

54. (Currently amended) The lead system according to claim 48, wherein the rigid elongated support structure has a mechanical memory such that the lead body retains a configuration after being shaped by a clinician under manual force and generally retains the

configuration after implantation pharmacological agent comprises an agent that promotes hemostasis or provides vasoconstriction.

55. (Currently amended) A system, comprising:

an implantable medical device, comprising:

a can that houses circuitry configured to provide one or both of cardiac monitoring and cardiac stimulation;

a lead coupled to the can, the lead comprising a lead body, a cardiac electrode coupled to the lead body, and one or more conductors coupled to the cardiac electrode and disposed within the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

a first pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body; and

a second pharmacological agent provided on a portion of an exterior surface of the can; and

a driver apparatus detachably coupled to the implantable medical device, the driver apparatus comprising a plurality of polyvinylidene fluoride layers and a plurality of conducting surface coatings each disposed along respective polyvinylidene fluoride layers of the plurality of polyvinylidene fluoride layers, the driver apparatus configured to facilitate sonophoresis delivery of at least one of the first pharmacological agent from the longitudinal portion of the exterior surface of the lead body and the second pharmacological agent from the portion of the exterior surface of the can by electrical activation of the conducting surface coatings and movement of the polyvinylidene fluoride layers.

56. (Currently amended) The system according to claim 55, wherein the lead comprises an rigid elongated support structure configured to stabilize and maintain a spacing between the cardiac electrode and the can in subcutaneous, non-intrathoracic tissue within the patient

~~driver apparatus facilitates electrophoresis delivery of at least one of the first and second pharmacological agents.~~

57. (Currently amended) The system according to claim-~~55~~ 56, wherein the ~~lead and the can form a unitary structure having an arcuate shape~~ ~~driver apparatus facilitates~~ ~~sonophoresis delivery of at least one of the first and second pharmacological agents.~~

58. (Currently amended) The system according to claim-~~55~~ 56, wherein the ~~rigid elongated support structure is configured to maintain the cardiac electrode and a second electrode disposed on the can in opposition with respect to the ventricles of the heart~~ ~~lead and the can are configured to produce an electric potential between the lead and the can to provide the~~ ~~phoresis delivery of at least one of the first and second pharmacological agents.~~

59. (Currently amended) The system according to claim 55, wherein the ~~polyvinylidene fluoride layers and the conducting surface coatings are provided at least along the longitudinal portion of the exterior surface of the lead body~~ ~~driver is configured to provide a phoresis power signal to the implantable medical device.~~

60. (Currently amended) The system according to claim-~~59~~ 55, wherein the ~~phoresis power signal is~~ ~~driver apparatus is configured to deliver~~ a DC voltage ~~to the conducting surface coatings to provide sonophoresis delivery.~~

61. (Currently amended) The system according to claim-~~59~~ 55, wherein the ~~phoresis power signal is~~ ~~driver apparatus is configured to deliver~~ an AC signal alternating at an ultrasonic frequency ~~to the conducting surface coatings to provide sonophoresis delivery.~~

62. (Currently amended) The system according to claim-~~59~~ 55, wherein the ~~phoresis power signal is~~ ~~driver apparatus is configured to deliver~~ a DC bias voltage with an AC signal

alternating at an ultrasonic frequency to the conducting surface coatings to provide sonophoresis delivery.

63. (Currently amended) The system according to claim-59 55, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driver apparatus facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy wherein at least one of the first and second pharmacological agents comprises an analgesic or an anesthetic.

64. (Currently amended) The system according to claim 55, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driver apparatus facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy wherein at least one of the first and second pharmacological agents comprises an antibiotic or an antiseptic.

65. (Currently amended) The system according to claim 55, further comprising an implantable pharmacological agent reservoir within the can wherein at least one of the first and second pharmacological agents comprises a steroid or an anti-inflammatory agent.

66. (Currently amended) The system according to claim-55 65, further comprising a micro-pump configured to facilitate transport of pharmacological agent from the reservoir to the exterior surface of the lead body and the exterior surface of the can wherein at least one of the first and second pharmacological agents comprises an agent that promotes hemostasis or provides vasoconstriction.